EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

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SUMMARY REPORT OF THE SECOND MEETING OF THE CHAIRS OF SCIENTIFIC COMMITTEES INVOLVED IN RISK ASSESSMENT (24 AND 25 OCTOBER 2006)

1. FIRST DAY MEETING

1.1 Introduction and objectives

Mr Madelin welcomed participants to the second meeting of the Chairs of Scientific Committees/Panels of Community bodies involved in risk assessment (see list of participants in Annex1). The objective of this second meeting was to discuss specific issues identified at the first meeting and activities that have developed since then. In this respect, the upcoming implementation of Registration, Evaluation Authorisation and Restrictions of Chemicals (REACH) which would have direct or indirect implications for most of the scientific committees/panels was presented and discussed. The issue of 'Risk evaluation and Risk management' starting from EMEA's experience, to be used as an example to illustrate possible tensions /problems that may be faced, was also discussed. Furthermore, Mr. Madelin proposed continuing the discussions on future developments and reiterated the need for a common framework for risk assessment which would be of benefit to all parties involved.

Day two would be divided into three discussion groups (dg): on emerging risks (dg1), alternative testing (dg 2) and nanotechnology (dg3).

1.2 Presentations and discussion on REACH

Representatives from the Joint Research Centre (JRC), Directorate Generals Environment (ENV) and Enterprise and Industry (ENTR) presented different aspects of the REACH programme, which are briefly summarised below.

The slides are available at the following web address
(http://ec.europa.eu/health/ph_risk/committees/ev_20061024_en.htm)

State of art and expectations in terms of data and risk assessment (Sharon Munn, JRC)
The background to the Commission proposal on REACH was described. REACH's basic goal was a regulatory instrument to ensure a high level of protection for human health and the environment as well as a free circulation of substances on the market. In addition, the speaker outlined one of the REACH Implementation Projects and the information requirements under REACH and described tests, adaptations and exceptions to testing. Art. 25.1 foresees that testing on vertebrates should be undertaken as a last resource and duplication of tests should be limited. The Annexes set out what should be done in the increasing amount of tests required as tonnage goes up. In the past the burden of proof was on public authorities, while under

REACH industry is responsible for risk assessment and it is their responsibility to justify which information they considered necessary. Authorities would have the opportunity to intervene if they felt that these risk assessments were not adequate. The Commission was assisting the implementation of REACH by drafting guidelines for industry with input from stakeholders, including industry. Intense preparatory work was being carried out on how to prepare chemical safety reports including information requirements. Guidance for authorities along the same lines was also being drafted.

Progress and prospective in relation to REACH Legislative Process (Bjorn Hansen, DG ENV)

Entry into force of the legislation was foreseen for April 2007. 2010 would be the first deadline for registration of existing substances above 1000 tonnes. The registration requirements would be staggered. Safety nets had been established to verify that chemical safety testing requirements had been complied with by industry. REACH introduced two new elements in risk assessment and one new element in data requirements, both in the guidance for industry and for authorities. The Derived No Effect Level (DNEL) concept had been introduced because in REACH the manufacturer and importer were responsible for hazard assessment and the end user for risk management. Exposure scenario now collected all the information necessary to control exposures to man and the environment in one place and thereby creating synergies from the risk management perspective.

Future Chemical Agency: structure, tasks, steps for its establishment (Joachim Kreysa, DG ENTR)

The structure of ECHA and practicalities of setting it up were described together with a timetable. 35 persons, who were currently undergoing training, would start in Helsinki, together with 40 Commission officials seconded from EC services. It was intended that the Agency would become operational in April 2008. The Chief executive would be appointed and recruit other members of the management team. The ECHA Committees would start work in the summer of 2008. They would deal with anything in relation to evaluation, authorisation, restriction, classification and labelling of substances. Adequate staffing levels would be required for 2010 when registration for all substances above 1000 tonnes started. A Board of Appeal would be set up.

Relationships of ECHA with other EU Agencies and impact of its implementation on the activities of their Scientific Committees/Panels and the Commission Scientific Committees (Reinhild Puergy)

The speaker outlined the impact of REACH and preliminary considerations for future coordination and relations between the EU agencies, Commission Scientific Committees and the ECHA.

The Agency would be an independent regulatory agency, managing technical, scientific and administrative aspects of REACH, have some decision-making powers and be assisted by Committees, e.g. a Risk Assessment Committee and a Socio-Economic Assessment Committee. ECHA might seek scientific advice from the Scientific Committees of SANCO on an ad hoc basis e.g. for seeking input on methodological questions and developments on new scientific approaches, the impact of new technologies such as nanotechnologies and other fields. Relations with other EU agencies might mainly focus on the exchange of information and experiences as well as establishing working arrangements between ECHA and other agencies. Cooperation between the European Food Safety Agency (EFSA) and ECHA on the classification and labelling of plant protection products might take place.

1.3 Discussion following the presentations

Several comments were made by Mr Madelin, Chairs and Vice-Chairs of Committees and Panels. In particular, several possible areas for concern were highlighted such as possible overlap in regulation as some substances might fall under REACH and other legislation (e.g. chemical substances, falling under REACH, subsequently being used in the food chain), potentially different opinions regarding risk assessment approaches, and a weakening of the separation between risk assessment and risk management. The need for the assessment of a substance in terms of worker protection and whether REACH would cover additional risk assessments was also stressed.

Possible confusion concerning the new terms employed under REACH (e.g. DNEL) was highlighted. Concerns were voiced about who would monitor the evaluation of data by industry and how harmonization would be ensured. The need to position risk assessment in a global world and to consider how to ensure consistency between the different agencies was underlined.

The Commission acknowledged that work was needed to strengthen links and information exchange between the agencies as it was important to keep track of risk assessments already performed. In the preparation of REACH, officials had tried to ensure there would be as little overlap in terms of scope of the risk assessments as possible (e.g. on pesticides). It was planned that a unit within ECHA would have some responsibilities for coordinating with other EU Agencies/bodies on such matters. Also in consideration of the international arena REACH had been designed following the existing Organization for Economic Cooperation and Development (OECD) chemical programme and guidelines. An obligation to consider international risk assessments and justify any deviation from them had been built into REACH. The Agency would probably need to give guidance to industry and Member States as to the mechanism for using such international risk assessments.

Harmonisation was crucial in terms of the introduction of new methodology. If an adequate method existed which did not use animal tests, then this method should be preferred. A lot of discussion had taken place on how to evaluate non-threshold effects. Substance evaluation would be the responsibility of Member States' competent authorities who would carry out the data quality evaluation. The Committee would then examine the position taken by the Member State in question. Good communication between Risk Assessors and Risk Managers at a technical level was vital for carrying out risk assessments that managers could use.

Presentation on 'Risk evaluation and risk management' (Dr Daniel Brasseur, Chair of the European Medicines Agency (EMEA) /CHMP (Committee for Medicinal Products for Human Use)

Dr Brasseur described how the members of the Committees at EMEA are nominated, and presented the centralised procedure used for marketing authorization for medicines. EMEA is in charge of both risk evaluation and risk management (through a pharmacovigilance plan submitted by Companies). EMEA also monitors the post marketing follow up. He outlined the roles and responsibilities of the different parties involved: marketing authorization holder, Member States, EMEA and the European Commission. EMEA is progressing from a system where decisions, historically taken on a purely national basis, are now shared and discussed on a European level. New legislation allowed EMEA to reconfirm at intervals the risk/benefit ratio of a drug to decide upon its maintenance on the market.

In response to questions from participants Dr Brasseur clarified that, although work was ongoing to identify validated criteria for a standard risk/benefit approach, currently such

criteria were not yet established. With respect to divergent opinions within the Committees, the Chairman would try to achieve consensus and although rarely not possible, the Committee would, in such case, proceed to a vote.

A representative of the European Environment Agency (EEA) called for consistency and coherence in the risk assessment terms used by the various agencies. The Commission informed participants of a forthcoming project concerning a comparative review of terminology and expressions used by the three current non-food Scientific Committees and also those used by the former committees. Layman language summaries of Scientific Committee Opinions were also being prepared.

With respect to the environmental impact of pharmaceuticals EMEA's power to influence the medical profession to choose a medicine which was less polluting was limited but it could issue warnings.

Conclusions of first day

Mr Madelin stressed that the issues raised in the presentations on REACH confirmed the need to identify the means of working together on common issues. A proposal to develop early co-operation between IT staff of the agencies (ECHA and other EU risk assessment bodies) facilitating access and exchange of data was discussed. It was proposed to develop a few case studies starting with the food area (e.g. Food Contact Materials (FCM), food additives and pesticides).

With regard to the 'risk evaluation and risk management' presentation, Mr Madelin underlined that the questions raised illustrated the common dilemmas faced. Here too the discussion had demonstrated a desire to identify common issues and case studies where there was a need to go further.

2. SECOND DAY MEETING

Paola Testori, acting Deputy Director General of DG Health and Consumer Protection, welcomed participants, who then took part in one of the three parallel discussion groups. Each discussion group was asked to share ideas on areas of mutual interest with a view to facilitating greater awareness and cooperation. They were also asked to identify main priority areas.

2.1 Discussion group 1 - Emerging risks (Chaired by Prof. V Silano)

The group exchanged ideas on areas of mutual interest such as activities in the area of emerging issues, with the aim of developing and improving cooperation. The conclusions were divided into three phases: phase 1 on "*Common understanding of what emerging risk is"*; phase 2 covered "*Exchange of information on mechanisms for Emerging risks assessment"* and phase 3 on "*Cooperation and way forward"*.

The group also discussed the need for background documents when drafting the paper on the way forward on cooperation. It considered the relevance of a global network in particular, learning from international initiatives (e.g. Canada, US). Some key areas were also discussed.

It highlighted the importance of:

- prevention and safety activities (e.g. The European Agency for Safety and Health at Work (OSHA), Bilbao – Report on emerging issues at the workplace

- developing a global approach, possibly including additional partners
- adoption of a proactive approach to identify areas where collaboration is possible (with easier access to this information)
- necessity for information screening, making an inventory of networks that e.g. monitor outbreaks (Rapid alert systems)
- aiming for a Europe-wide system to screen new hazards
- focussing on new technologies to identify emerging risks (e.g. Nano, particle-size reduction in diesel emissions, new aerosol composition)
- considering re-emerging issues and changes in disease and outbreak patterns

A proposal was made for a draft document on emerging risks where all the main bodies operating at a European or international level should be identified as possible partners of this European undertaking. Prof. Silano offered to contribute to the ad-hoc paper as a starting point.

DG ENTR also mentioned the existing network on European Technology Platforms on industrial safety (ETPIS) linked to the establishment of a network and other activities linked to emerging risks (see also www.industrialsafety-tp.org).

2.2 Discussion Group 2: Alternative Testing (Chaired by Prof H Greim)

The group was invited to discuss in particular the following issues:

- Criteria for replacement of animal testing
- Reduction and refinement, intelligent testing strategies
- Current knowledge
- Future developments, realistic time tables
- Practical prospects of using alternative testing in risk assessment
- Validation and acceptance issues

It was explained that the three Scientific Committees had been asked several times for opinions on alternatives to animal testing. These opinions, available to this group, as background documents, were considered too conservative since the Scientific Committees stated that current alternative tests do not sufficiently address a complete risk assessment but could only be used for certain endpoints. This was reiterated in a joint statement made by the Scientific Committees.

In this respect a member of the group highlighted that this may be a misunderstanding of the alternative test use in risk assessment. However, the alternative testing might be indirectly used in the hazard identification process. In the risk assessment alternative tests might not be used as a pivotal study i.e. to fix an Acceptable Daily Intake (ADI) value but in order to decide which targets have to be taken into account, data could also originate from published literature where alternative testing was used.

The meeting proceeded with the compilation of a table which included current knowledge, future developments and realistic time tables for validation of alternatives. The table that presented the validated test and those under discussion for validation was discussed in detail. The following was agreed:

- The European Centre for the Validation of Alternative Methods (ECVAM) will update the table with additional information, as soon as the discussion and ongoing works were concluded. It will also add information on the future timetable. The new information

sent by ECVAM will be used to update the report and would be circulated to the group for approval (possibly by end of the year/beginning of 2007).

The group also concluded that:

- Validated alternative to animal testing should be used when the ability to assess chemical/product safety is not compromised. Progress on development and validation of alternative tests was encouraged by the group.
- Intelligent testing was recommended since it could reduce the need for additional animal studies (tiered approach, Threshold of toxicological concern (TTC)) and Quantitative Structure-Activity Relationships (QSARs).
- Quality assurance needed to be demonstrated. Harmonisation of approaches was necessary. More exchange of information among different groups (chemicals, food and pharmaceuticals) was suggested since similar procedures were sometimes developed in parallel by different bodies.

2.3 Discussion Group 3 : Nanotechnologies (Chaired by Prof. J Bridges)

The Chair drew the attention of the participants to the on-going work on the risk assessment of nanomaterials in the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Scientific Committee on Consumer Products (SCCP) and in EMEA/CHMP. The issue had also been discussed in the EFSA Advisory Forum, which recognised the need for a follow-up.

A definition of nanomaterials and the need for a common approach on a better evaluation of the safety and competitiveness of nanotechnologies including risk assessment was recognised. The group discussed the relevance of a proactive role of the Scientific Committees and of their timely inputs to research and policy making. The on-going international work on nanotechnologies, to which the work of the Committees may contribute, was also considered.

The group recognised the need for cooperation and exchange of information between the Scientific Committees in this field. This was underlined in view of the similarities as well as the differences between the nanotechnology-based applications which the Scientific Committees needed to assess. The need for international data bases on both products and on scientific data was also acknowledged.

Attention was drawn to the issue of confidentiality which might hinder the exchange of information between the committees, although Regulation 1049/2001 provides a common approach for Scientific Committees with regard to industry data. With respect to the Intellectual Property Rights (IPR) issues of research data, the possibility of using intermediate reports for risk assessment (e.g. in BSE) could be considered.

With respect to the on-going work in ISO/CEN on the terminology for nanotechnologies, the Scientific Committees needed to follow the work and contribute to the issues related to their areas of work.

The group concluded that:

- Participants should be invited to comment on the SCENIHR opinion, to work towards a converging approach to a coherent risk assessment of nanomaterials and to assess whether the approach presented would be suitable for their work area. If this is not the case the difficulties and needs for a modified approach should be explained.

- SANCO C7 would investigate the possibility of establishing a CIRCA platform for the exchange of information between Secretariats on nanotechnology issues related to risk assessment.
- SANCO Workshop between stakeholders and risk assessors on the nanotechnology applications should take place in Brussels in mid-2007.
- The SCENIHR would provide a Check List for the assessment of risks related to nanomaterials and would send it for comments to other Scientific Committees.

DG ENTR highlighted the numerous other activities which are ongoing for implementation of European Regulations (for instance the various European Technology Platforms, e.g. on sustainable chemistry and on industrial safety, and the OECD activities).

2.4 Overall conclusions

Mr Madelin concluded that the meeting had discussed high level objectives for a shared approach to risk assessment but had also identified more operational issues (see Annex.2).

The key elements of our endeavour were:

- An excellent, recognised common approach, including the general principles for RA across sectors; common methodological approach on controversial issues; engagement with stakeholders and internationally
- Clear and effective risk communication: consistent and clear terminology; clear description and expression of the scope and nature of risks, of uncertainties and their implications;
- A framework for EU and international co-operation: procedures, respectful of confidentiality, for the exchange of data and information; co-operation for comprehensive (multi-source) risk assessment.

The follow-up to the meeting would include a table on a shared approach to best practice in risk assessment. A list of activities (action plan) and deliverables would include:

- SANCO C7 to prepare the initial draft, in cooperation with Prof Silano and EFSA, of a common paper on the concept of emerging risks and the approach for their identification and assessment. The discussion group participants would also be asked to read/provide input.
- Establishing a road map to identify and assess risks related to nanotechnology. All bodies were invited to comment on the SCENIHR opinion and designate contact points by 30 November.
- SANCO C7 to circulate a list and establish an IT tool for the exchange of information/dialogue. SCENIHR to establish a checklist for the assessment of risks related to nanomaterials and an inventory of current relevant activities.
- Establishing cooperation for monitoring developments on alternative testing including a finalized and updated table as discussed at the meeting. Each committee/panel should refine the current alternative testing inventory and the issue is for reconsideration at the third Chairs' meeting.
- Examining the impact of the establishment of ECHA: preparing for coordination and cooperation by developing a few case studies, making an inventory of borderline issues and ensuring early cooperation between IT staff to facilitate access and exchange of data.
- Finalising and applying procedures for the early identification of possible divergent opinions, based on the EMEA reflection paper; commenting on EMEA's list of

activities and sharing a document prepared by EMEA and the European Centre for Disease Prevention and Control (ECDC) on vaccines/pandemics.

- Finalising common guidelines on confidentiality/exchange of information. SANCO C7 had prepared a first draft circulated for comments to all secretariats.
- Promoting international cooperation and consistency on risk assessment.

3. 2ND DAY - MEETING BETWEEN SECRETARIATS/COORDINATORS AND COM SERVICES

After summarising the outcome of the activities from the first meeting and the progress made on each action (table distributed for information to the group) consideration was given to the documents tabled for discussion, in particular to the following: the EMEA reflection paper; the EMEA's list of activities for possible cooperation; the SANCO.C7 and SCs' comments to the EMEA list, the SANCO SCs' list of activities for possible cooperation; and the first draft on confidentiality/exchange of dossiers. The SANCO SCs' work programme was also distributed for information.

With respect to the EMEA reflection paper it was agreed that EMEA would finalise its document on diverging opinions and each body would prepare a draft as far as possible in line with EMEA's proposal. SANCO agreed to be fully in line with it while EFSA will follow the principle but in less detail. Each document should be shared and discussed by the end of November. It should be noted that DG ENTR favoured a joint document. In this respect the EEA took note of this paper but signalled the different mandate of its SC and therefore the non applicability of such a document. It expressed interest in the project on common terminology.

With regard to EMEA's list of activities for cooperation it was agreed that the SANCO.C7 comments would be incorporated. EFSA favoured more bilateral contacts among committees/panels. EFSA also highlighted the workload involved and the unlikelihood of getting all the information needed. It was underlined that this should be considered as an attempt to improve cooperation and get an advance forecast of possible overlapping subjects. EMEA believed this would demonstrate a proactive attitude between bodies vis-à-vis their responsibility to avoid divergences. EFSA proposed that the Commission should be responsible for an overview of activities. This was considered unacceptable as part of this responsibility lies with responsible bodies, based on the respective legislation.

The SANCO SCs work programme was presented for information. The JRC suggested adding an overview of upcoming questions on existing substances to the Scientific Committee on Health and Environmental Risks (SCHER) before REACH took over.

A first draft on confidentiality/exchange of document was tabled for discussion. This issue raised a number of questions in relation to data protection, particularly for the EMEA Committees and the Additives and Products or Substances used in Animal Feed (FEEDAP) & Genetically Modified Organisms (GMO) Panels in EFSA. The draft will be re-circulated among secretariats for comment by the end of November. On the basis of the discussion it was agreed to re-consult the Commission's Legal Service (LS), to clarify certain aspects with respect to the practical implementation by committees/panels and data protection (e.g.: GMO panel). Each body was invited to contribute to the questions to be posed/clarified by the LS. ENTR also advised involving the colleagues responsible for medicinal products in LS. It was agreed that comments /questions should be sent by the end of November and that all key people should be copied in the note.

Follow-up to morning sessions:

The group reconsidered the morning discussion, and based on REACH presentations, agreed that 3-4 pilot case studies could be considered, in particular in the food area (e.g.: on Food Contact Materials (FCM) and food additives). REACH colleagues would be contacted and involved in the exercise. Interaction between persons in charge of information technologies (IT) to access data was also suggested. This would be included in the follow-up activities table.

The EMEA and the ECDC agreed cooperation on pandemic/vaccines and stated they were also available to share their first draft document for cooperation.

With regard to the discussion group on nanotechnologies, it was agreed that the SCENIHR would prepare a checklist for the assessment of risks related to nanomaterials. The SCENIHR would also work on the feasibility of a Circa network. The participants agreed to comment on the SCENIHR opinion by the end of November. They also agreed that contact points would be designated by the end of November. SANCO also informed the group of the intention to organise a workshop (tentative date: February 2007, to be confirmed).

In the discussion group on emerging risks it was agreed that a paper would be prepared by SANCO.C7 in collaboration with Prof Silano, EFSA together with the discussion group participants, who had also agreed to read/provide input. Tentative areas of common interest were briefly mentioned within the group.

With respect to the discussion group on alternative testing it was agreed to finalise the timetable presented at the meeting. Each Committee/Panel was invited to refine the current alternative testing inventory. The JRC would complete/update the table and EMEA would then circulate it to the entire group.

A lot of discussion centred on the opening/closing slide, presented by Mr Madelin. It was finally agreed to add it to the report of the meeting. Comments to the slide indicated replacing 'controversial issues' with 'difficult issues' and separating 'International engagement' from 'stakeholders' engagement'. It was also proposed changing the wording 'engagement' into 'dialogue'.

It was concluded that a letter from Mr Madelin, including a table on follow-up activities to this meeting would be sent by middle November 2006 covering operational stages, progress made and activities for agencies.

Annex 1
List of participants

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
Ms Maria Pilar AGUAR FERNANDEZ	European Commission DG RTD.G4	Research Programme Officer – Nanotechnology 'Nano S&T – Convergent Science and Technology'
Ms Ebba BARANY	European Commission DG RTD.E3	Research programme officer- Project management – negotiation – evaluation 'Food – Health – Well being'
Dr Susan BARLOW	(EFSA)	Chair of the AFC Panel on food additives, flavourings, processing aids and materials in contact with food
Mr Achim BOENKE	European Commission DG ENTR.G2	Policy officer - Desk officer chemicals 'Chemicals'
Dr Daniel BRASSEUR	(EMEA)	Chair of the CHMP Committee for Medicinal Products for Human Use
Mr Siegfried BREIER	European Commission DG ENTR.F.3	Policy Desk Officer -Cosmetics 'Cosmetics and Medical Devices'
Prof. James BRIDGES	(DG SANCO.C7)	Chair of the SCENIHR Scientific Committee on Emerging and Newly Identified Health Risks

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
Ms Katja BROMEN	European Commission DG SANCO.C7	Scientific Secretariat of the SCENIHR Scientific Committee on Emerging and Newly Identified Health Risks
Mr Juergen BÜSING	European Commission DG RTD.I3	Research Programme Officer 'Environmental technology – pollution prevention'
Ms Elzbieta CEGLARSKA	EFSA	Scientific Co-ordinator PLH Panel on plant health
Prof. Andrew CHESSON	(EFSA)	Chair of the FEEDAP Panel on additives and products or substances used in animal feed
Prof. John Dan COLLINS	(EFSA)	Chair of the BIOHAZ Panel on biological hazards
Mr Panagiotis DASKALEROS	European Commission DG SANCO.B3	Policy desk officer 'Product and service safety'
Mr Bernardo DELOGU	European Commission DG SANCO.C7	Head of Unit 'Risk Assessment'
Ms Muriel DUNIER-THOMANN	EFSA	Scientific Co-ordinator PPR Head of Team of PPR Activities Panel on plant protection products and their residues
Ms Gigliola FONTANESI	European Commission DG SANCO.C7	Scientific Secretariat of SCHER Scientific Committee on Health and Environmental Risks
Ms Anne GAUTRAIS	European Commission DG ENTR.F2	Policy Officer - Veterinarian Pharmaceuticals
Mr David GEE	EEA	Group Leader 'Science, policy and innovation'

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
Prof. Johan GIESECKE	ECDC	Head of Unit 'Scientific Advice'
Prof Helmut GREIM	(DG SANCO.C7)	Chair of the SCHER Scientific Committee on Health and Environmental Risks
Ms Kornelia GREIN	EMEA	Head of Sector 'Safety of Veterinary Medicines'
Ms Karola GRODZKI	European Commission DG ENTR.G2	Policy officer - Desk officer chemicals 'Chemicals'
Mr Bjorn HANSEN	European Commission DG ENV.D1	Deputy Head of Unit 'Chemicals'
Prof. Anthony R. HARDY	(EFSA)	Chair of the PPR Panel on plant protection products and their residues
Dr Thomas HARTUNG	European Commission DG JRC.I2	Head of Unit 'Validation of biomedical testing methods'
Ms Galina Georgieva HRISTOVA	EEA	Secretariat of Scientific Committee and of Management Board Corporate Affairs
Ms Marta HUGAS	EFSA	Scientific Co-ordinator BIOHAZ Panel on biological hazards
Ms Athanasia KANELLOPOULOU	European Commission DG SANCO.C7	Trainee 'Risk Assessment'
Ms Sheila KENNEDY	EMEA	Regulatory Affairs and Organisational Support Sector
Ms Juliane KLEINER	EFSA	Senior Scientific Officer Risk Assessment
Mr Joachim KREYSA	European Commission DG ENTR.G1	Head of Section - Head of Interim Strategy Team 'REACH'
Dr Harry A KUIPER	(EFSA)	Chair of the GMO Panel on genetically modified organisms
Dr. Zsuzsanna JAKAB	ECDC	Executive Director
Dr. Pierre LACONTE	(EEA)	Member of the Scientific Committee
Mr Djien LIEM	EFSA	Head of Team on Horizontal Scientific Issues - Scientific Coordinator of the Scientific Committee
Mr Robert MADELIN	European Commission DG SANCO	Director General
Ms Marina MARINI	European Commission DG SANCO.C7	Scientific Officer 'Risk Assessment'

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
Ms Barbara MENTRE	European Commission DG ENTR.F3	Policy Desk Officer - Cosmetics 'Cosmetics and Medical Devices'
Dr Gérard MOULIN	(EMEA)	Chair of the CVMP Committee for Medicinal Products for Veterinary Use
Ms Sharon MUNN	European Commission DG JRC.I.03	Scientific officer 'Toxicology and chemical substances'
Mr Jan MUYLDERMANS	European Commission DG SANCO.C7	Administrative Assistant 'Risk Assessment'
Ms Arielle NORTH	EMEA	Directorate - Executive Support
Ms Annette ORLOFF	European Commission DG ENTR.F3	Policy Desk Officer Cosmetics 'Cosmetics and Medical Devices'
Ms Terje PEETSO	European Commission DG SANCO.C6	Legislative officer - Policy officer 'Health measures'
Mr Aurelien PEREZ	European Commission ENTR.F.2	Administrative assistant for medicinal products authorisation 'Pharmaceuticals'
Ms Maila PUOLAMAA	European Commission DG SANCO.C7	Scientific Secretariat of SCCP Scientific Committee on Consumer Products
Ms. Reinhild PÜRGY	European Commission DG ENV.D1	Policy Officer Endocrine Strategy 'Chemicals'
Ms Susy RENCKENS	EFSA	Scientific Co-ordinator of the GMO Panel on genetically modified organisms
Ms Pilar RODRIGUEZ - IGLESIAS	EFSA	Scientific Co-ordinator of the NDA Panel on dietetic products, nutrition and allergies
Ms Claudia RONCANCIO PENA	EFSA	Senior Scientific Officer – Risk assessment Panel of additives and products or substances used in animal feed
Mr Andrzej RYS	European Commission DG SANCO.C	Director 'Public Health and Risk Assessment'
Dr. Jan SCHANS	(EFSA)	Chair of the PLH Panel on Plant Health
Dr Josef Rudolf SCHLATTER	(EFSA)	Chair of the CONTAM Panel on contaminants in the food chain
Mr Stefan SCHRECK	European Commission DG SANCO.C3	Acting Head of Unit 'Health threats'

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
Prof. Vittorio SILANO	(EFSA)	Chair of the Scientific Committee
Mr Stefano SORO	European Commission DG SANCO.B3	Head of Unit 'Product and service safety'
Ms Maria SPULBER	European Commission DG RTD.E3	Research Programme Officer 'Food – Health – Well being'
Ms Paola TESTORI-COGGI	European Commission DG SANCO	Acting Deputy Director General
Mr Andrea TILCHE	European Commission DG RTD.I3	Head of Unit 'Environmental technology – pollution prevention'
Mr Antoon VAN ELST	European Commission DG SANCO.C7	Technical Assistant – Scientific Secretariat of SCCP Scientific Committee on Consumer Products
Mr Robert VANHOORDE	European Commission DG SANCO.03	Head of Unit 'Science and stakeholder relations'
Dr Philippe VANNIER	(EFSA)	Chair of the AHAW Panel on animal health and welfare
Ms Birgit VAN TONGELEN	European Commission DG ENV.B3	Policy officer – Environment and Health 'Biotechnology, Pesticides and Health'
Mr Juergen VOGELGESANG	European Commission DG SANCO.B3	Policy desk officer 'Product and service safety'
Mr Michael WALSH	European Commission DG SANCO.03	Deputy Head of Unit 'Science and stakeholder relations'
Dr Ian WHITE	(DG SANCO.C7)	Chair of the SCCP Scientific Committee on Consumer Products

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<u>Administrative support</u> :		
Ms Carol HUMPHREY-WRIGHT	European Commission DG SANCO.C7	Assistant to Head of Unit 'Risk assessment'
Ms Cathy DEKINDT	European Commission DG SANCO.C7	Secretary of the SCCP and SCHER 'Risk Assessment'
Ms Corinne DE LEENHEER	European Commission DG SANCO.C7	Interimaire 'Risk Assessment'
Ms Nathalie FOUVEZ	European Commission DG SANCO.C7	Secretary of the SCENIHR 'Risk Assessment'
Ms Manuela GAGGINI	European Commission DG SANCO.C7	Secretary to Head of Unit 'Risk Assessment'

Annex 2

A shared Approach to Best Practices in Risk Assessment (RA)

EU Risk Assessment Bodies operate within a global framework (e.g. Codex etc) and within distinct sets of EU legal requirements. Within these constraints, we have decided as Chairs and Co-ordinators of EU risk assessment process to work together more closely in pursuit of a common framework for RA.

Such a framework would generate greater public recognition of the value added of EU scientific RA, and would drive the pursuit of better quality Risk Management decisions.

The key element of our endeavour are :

- **An excellent, recognised common approach, including :**
  - ✓ *General principles for RA across sectors*
  - ✓ *Common methodological approach on controversial issues*
  - ✓ *Engagement with stakeholders and internationally*

- **Clear and effective Risk Communication**
  - ✓ *Consistent and clear terminology*
  - ✓ *Clear description and expression of the scope and nature of risks, of uncertainties and their implications*

- **A framework for EU and international co-operation**
  - ✓ *Procedures, respectful of confidentiality, for the exchange of data and information*
  - ✓ *Co-operation for comprehensive (multi-source) risk assessment*